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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1458]

Draft Guidance for Infant/Child Apnea Monitor 510(k) Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for Infant/Child Apnea Monitor 510(k) Submissions.'' This guidance is not final nor is it in effect at this time. This draft guidance describes minimum performance, testing, labeling, and clinical criteria for the infant/child monitor. Upon considering comments on the draft document, FDA will modify the guidance so that it is applicable to apnea monitors for patients of all ages. Elsewhere in this issue of the **Federal Register**, FDA is proposing to classify the apnea monitor into class II with this guidance document as the special control. FDA is issuing this draft guidance because the agency believes it is necessary to provide reasonable assurance of the safety and effectiveness of the apnea monitor.

DATES: Submit written comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Guidance for Infant/Child Apnea Monitor 510(k) Submissions'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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Comment should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Joanna H. Weitershausen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 164.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 21, 1995 (60 FR 9762), FDA issued a proposed rule setting forth requirements for a mandatory performance standard for the infant apnea monitor (hereinafter referred to as the 1995 proposal). Elsewhere in this issue of the **Federal Register**, FDA is withdrawing the 1995 proposal. Because of reduced mortality rates for infants at risk for death due to apparent life-threatening events, and after considering other factors, FDA no longer believes that a mandatory performance standard is needed for this class II device.

In conjunction with the withdrawal of the 1995 proposal, FDA is proposing also to create a separate classification for the apnea monitor device. This proposal, which also appears elsewhere in this issue of the **Federal Register**, will remove apnea monitors from their current classification within the generic type of device known as the breathing (ventilatory) frequency monitor (21 CFR 868.2375). The proposed rule will classify the apnea monitor as a group in class II (special controls), with an industry guidance document issued by FDA as the special control. The generic apnea monitor will include devices used to monitor apnea, i.e., the cessation of breathing, in all patient populations. The infant/child apnea monitor used on infants and children under 3 years of age will fall within the generic type of device proposed for classification as the apnea monitor.

The draft guidance describes minimum performance characteristics, testing procedures and criteria, labeling, and, as appropriate, clinical testing recommendations for infant/child apnea monitors. After considering comments on this draft guidance and further evaluating appropriate

clinical study parameters, FDA intends to modify the guidance so that the final guidance document is applicable as the special control for the apnea monitor used on patients in other age groups, as well as infants and children.

II. Significance of Guidance

This guidance document represents the agency's current thinking on infant/child apnea monitor 510(k) submissions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. As noted above, the agency believes the performance, testing, labeling, and clinical criteria in this draft guidance are applicable as well to apnea monitors used on patients of other ages. FDA intends to modify the final guidance document accordingly. FDA invites comments on how this guidance may be adapted to apply to apnea monitors used on patients other than infants and children.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Guidance for Infant/Child Apnea Monitor 510(k) Submissions'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number (1178) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated

on a regular basis, the Center for Devices and Radiological Health (CDRH) home page includes "Guidance for Infant/Child Apnea Monitor 510(k) Submissions," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. "Guidance for Infant/Child Apnea Monitor 510(k) Submissions" is available at http://www.fda.gov/cdrh/ode.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may

submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/1/00
September 1, 2000

Linda S. Kahan

Linda S. Kahan
Deputy Director for Regulations
Policy, Center for Devices and Radiological Health

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